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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\# **CNR No. DLHC010111402026**

\+ CS(COMM) 293/2026

NOVARTIS AG & ANR. .....Plaintiffs

Through: Mr. Amit Sibal, Sr. Advocate with Mr. Abhay Tandon, Mr. Hemant Singh, Ms. Mamta Jha, Ms. Kriti Chulet, Mr. Ritik G., Mr. Saksham Dhingra and Ms. Smriti Nair, Advocates.

versus

BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED & ANR. .....Defendants

Through: Mr. J. Sai Deepak, Sr. Advocate with Ms. Meenakshi Ogra, Mr. Tarun Khurana, Mr. Samrat S. Kang and Mr. Vishnu Gambhir, Advocates.

CORAM:
HON'BLE MR. JUSTICE A. J. BHAMBHANI

O R D E R

% 17.08.2026

The matter has been listed upon being released by the Predecessor Bench.

I.A. 7599/2026 (seeking leave to deliver interrogatories and production of document)

I.A. 7600/2026 (seeking leave of the court to redact the names of the third-parties in the RTI response)

Issue notice.

2. Learned counsel is present on behalf of the defendants; accepts notice; and seeks time to file replies.

3. Let replies to the applications be filed within 04 weeks; rejoinder(s) thereto, if any, be filed within 03 weeks thereafter; with copies to the opposing counsel.

4. List before the learned Joint Registrar for completion of pleadings on 17th November 2026.

5. List before court thereafter.

I.A. 12145/2026 (filed by defendants seeking return of plaint)

6. Issue notice.

7. Learned counsel is present on behalf of the plaintiffs; accepts notice; and seeks time to file replies.

8. Let replies to the application be filed within 04 weeks; rejoinder(s) thereto, if any, be filed within 03 weeks thereafter; with copies to the opposing counsel.

9. List before the learned Joint Registrar for completion of pleadings on 17th November 2026.

10. List before court thereafter.

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11. Let the plaint be registered as a suit.

12. Issue summons in the suit.

13. Learned counsel is present on behalf of the defendants; accepts summons; and seeks time to file written statements.

14. Let the written statements to the plaint be filed within 30 days, alongwith affidavit of admission/denial of the documents filed by the plaintiffs. The plaintiffs may file replications to the written statements within 30 days thereafter, alongwith affidavit of admission/denial of the documents filed by defendants.

15. List before the learned Joint Registrar for completion of pleadings, for admission/denial of documents and marking of exhibits on 17th November 2026.

16. List before court thereafter.

I.A. 7597/2026 (interim injunction)

17. The matter is pending at the pre-notice stage since 23.03.2026.

18. Issue notice.

19. Learned counsel is present on behalf of the defendants; accepts notice; and seeks time to file reply.

20. As recorded in para 10 of order dated 23.03.2026, Mr. J. Sai Deepak, learned senior counsel appearing for the defendants had made the following submissions:

> *"10. Mr. J. Sai Deepak, learned senior counsel for defendants, after some arguments, under instructions submits that the three issues which should ordinarily allay the apprehension of the plaintiffs qua the quia timet action are as under:*
>
> *(i) The defendants do not have any commercial license to manufacture the compound/product in question from any authority.*
>
> *(ii) He also submits that the license, which according to the plaintiffs has given rise to the apprehension, is limited in its purpose, in that, the scope of the license is only for manufacturing drugs for the purposes of examination, test or analysis. He further clarifies that the said license also has proscribed its effect by specifically stating "Not for clinical trial unless or otherwise permitted by the licensing authority".*
>
> *(iii) He submits that at this stage, the protection granted under the provision of Section 107A of the Patents Act, 1999, is fully in favour of the defendants and the defendants are entitled to continue with the examination, test*

and analysis of the said compound till an appropriate license is issued in its favour."

21. On the other hand, Mr. Amit Sibal, learned senior counsel appearing for the plaintiffs submits that the plaintiffs' apprehension, based on which they have filed the present suit, arises from an RTI response dated 17.10.2025 received by them from the Commissioner of Foods and Drugs Control Administration, Gandhinagar, Gujarat, which *inter-alia* stated the following:

Sr. No.	***Details***	***Information***
APPLICATIONS FOR MANUFACTURING LICENSES FOR DEBRAFENIB		
1	*Please confirm whether the entity/entities have submitted an application to your office for obtaining manufacturing license/approval for manufacturing and/or sale of DABRAFENIB and/or its pharmaceutical salts, active pharmaceutical ingredient (API), bulk drug and/or formulation containing DABRAFENIB and/or its pharmaceutically salts for export and/or domestic market?*	*This Department doesn't maintain separate records, however by checking online database it's found that, entity/entities have applied for obtaining manufacturing license/approval for manufacturing of DABRAFENIB active pharmaceutical ingredient (API) and/or DABRAFENIB tablets for export and/or domestic market.*
GRANTED MANUFACTURING LICENSES FOR DABRAFENIB		
4	*Please confirm whether a manufacturing license/approval has been granted to any entity/entities in relation to DABRAFENIB or its salt/API/formulation for manufacture/export/any other use, either for API or bulk drug or formulation of DABRAFENIB*	*This Department doesn't maintain separate records, however by checking online database it's found that, this office has granted manufacturing license/approval to entity/entities for manufacturing DABRAFENIB API and/or DABRAFENIB tablets for export and/or domestic market.*

5	*Reference to question 4, kindly provide us with the name(s) and address(s) of such entity/entities that have been granted the manufacturing license/approval.*	*Name(s) and address(es) of the entity/entities granted the manufacturing license/approval are* ***(redacted part)*** *2. M/s. BDR lifesciences pvt ltd, 3. BDR pharmaceuticals internation pvt ltd* ***(redacted part)***

22. Furthermore, Mr. Sibal points-out that in compliance of order dated 23.03.2026, the defendants have filed an affidavit dated 25.03.2026 stating *inter-alia* that defendants Nos.1 and 2 have obtained licence to manufacture the drug 'DABRAFENIB' strictly for the limited purpose of examination, testing and analysis and that the license does not extend to or permit usage for clinical trial, except where specific permission is obtained from the competent licensing authority in accordance with law.

23. Mr. Sibal submits however, that in case of an Active Pharmaceutical Ingredient ('API'), no clinical trials are required; and therefore, the apprehension of the plaintiffs, which is the basis of the present *quia timet* action, is justified. Learned senior counsel submits therefore, that to that extent para 5 of affidavit dated 25.03.2026 filed by the defendants is inaccurate and misleading.

24. Mr. J. Sai Deepak, learned senior counsel appearing for the defendants, on the other hand, asserts that the only licence that the defendants presently hold is for manufacturing the drug for the purposes of examination, testing and/or analysis and that bioequivalence studies on the formulation are necessary. Learned senior counsel therefore submits that the defendants are nowhere close to the stage of commercially manufacturing, distributing or marketing even the API product.

25. Mr. Sibal has contested the submissions so made.

26. In the circumstances obtaining in the matter, and in view of the defendants' own submission that they are nowhere close to obtaining a license for manufacturing, distributing or marketing 'DABRAFENIB' as an API or as tablets, it is directed that *before* taking any steps towards commercial manufacturing or launch of 'DABRAFENIB' as an API or as tablets for export and/or for the domestic market, as indicated in the RTI response extracted above, the defendants shall move an appropriate application before this court seeking *prior approval* for that purpose. On such application being moved, this court would consider if any further orders are required to be passed in relation to the relief prayed-for by the plaintiffs in this application.

27. Let reply to the present application be filed within 04 weeks; rejoinder(s) thereto, if any, be filed within 03 weeks thereafter; with copies to the opposing counsel.

28. List before the learned Joint Registrar for completion of pleadings on 17th November 2026.

29. List before court thereafter.

30. The objections taken by the defendants in their application filed under Order VII Rule 11(a) & (d) of the Code of Civil Procedure 1908 shall be considered before any other applications are taken-up in the present proceedings.

A. J. BHAMBHANI, J

AUGUST 17, 2026
V.Rawat